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**Date:** 7/12/2016

**GAIN Report Number:** RS1634

# **Russian Federation**

Post: Moscow

# Russia Bans Cultivation and Breeding of GE Crops and Animals

## **Report Categories:**

Biotechnology - GE Plants and Animals Policy and Program Announcements

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#### **Report Highlights:**

On July 3, 2016, President Putin signed Federal Law 358-FZ "On amendments to certain legislative acts of the Russian Federation concerning improvement of the state regulation in the sphere of genetic-engineering activities." These amendments prohibit cultivation of genetically engineered plants and breeding of genetically engineered animals on the territory of the Russian Federation, strengthen state control and monitoring of processing and imports of GE organisms and products derived from such organisms and set penalties for violations of this federal law.

Note: All Russian legislative and regulatory documents use the term GMO (genetically modified organisms) or GMM (genetically modified microorganisms) instead of genetically engineered (GE) organisms/microorganisms. Therefore, throughout this report, when referring to language in those documents, we will default to the terms as used in the document.

#### **General Information:**

President Vladimir Putin signed Federal Law No 358 of July 3, 2016 "On amendments to certain legislative acts of the Russian Federation concerning improvement of the state regulation in the sphere of genetic-engineering activities." These amendments prohibit cultivation of genetically engineered plants and breeding of genetically engineered animals on the territory of the Russian Federation, except for cultivation and breeding of plants and animals required for scientific expertise or research. The amendments provide that controlling bodies of the executive power shall monitor: the effects of GE organisms, and products derived from such organisms, not only on the environment but also on the health of human beings; shall conduct state registration of such organisms and products, and in case of violations may ban imports of such products. The penalties for officials, violating this law, will be from 10,000 rubles to 50,000 rubles. The penalties for juridical persons violating this law will be from 100,000 rubles to 500,000 rubles<sup>1</sup>. Federal Law 358 will come into force on the date of its official publication (July 4, 2016), except the article pertaining to penalties in case of violations, which will come into force on July 1, 2017.

Federal Law 358 amends four major legislative acts of the Russian Federation:

- 1. Federal Law of July 05, 1996, No. 86-FZ "On the State Regulation in the Sphere of Genetic-Engineering Activity." The amendments emphasize the role of state control over the release of genetically-engineered organisms into the environment, state monitoring of the effects of such release on the environment and also on the health of human beings. The amendments add the responsibility of control and monitoring, as well as registration, of genetically engineered organisms and products, including imported goods, to the state. The amendments broaden the meaning of "safety control in the sphere of genetic engineering," and emphasize that, based on the results of monitoring the effect of GE organisms and products on environment and human health, the authorized bodies of the executive power can ban imports of genetically-engineered organisms and/or products derived from GE organisms into Russia;
- 2. Federal Law of December 17, 1997, No. 149-FZ "On Seed Industry." The amendments to this FL ban imports of GE planting seeds into Russia, with the exception of sowing (planting) such seeds "in the course of expert examination and research activities;"
- 3. Russian Federation Code of Administrative Offences. The amendments to this Code specify penalties for violations of the legislation of the Russian Federation in the sphere of genetic engineering (from 10,000 rubles to 50,000 rubles for officials, and from 100,000 rubles to 500,000 rubles for individuals from the judiciary), and specifies the bodies of the executive power which can consider violations;
- 4. Federal Law of January 10, 2002 No, 7-FZ "On Protection of the Environment." The amendments to this FL ban growing and/or breeding of genetically –engineered (modified) plants and animals in the territory of the Russian Federation, except growing and breeding of such plants and animals in

<sup>&</sup>lt;sup>1</sup> At the time of signing the FL 358 of July 3, 2016, the exchange rate was 64 rubles per \$1.

the course of expert examination and research activities.

The unofficial translation of the Federal Law No. 358 of July 3, 2016 is given below.

### **Background information**

Until adoption of the Federal Law 358 on July 3, 2016, the ban on cultivation of GE crops and breeding of animals existed de-facto because there were no administrative mechanisms for registration of genetically engineered crops and animals for release into environment. In October 2010, on the eve of WTO accession, Russia adopted a Federal Law that allowed the Government to regulate issues of genetic engineering through legislative documents at the government level. Thus, in September 2013 the Russian Government issued Resolution No. 839<sup>2</sup> that allowed for the development of a mechanism for the registration of GE crops for release into the environment (i.e. cultivation), and set July 1, 2014 as the date of initiation of this mechanism for the registration of GE crops for release into environment. Industry analysts estimated the registration process for GE crops for cultivation would take approximately five to six years. With this estimate, it was anticipated that the initiation of cultivation of such crops in Russia would not begin before 2023 to 2024. Resolution No. 839 caused a mass media and public campaign that argued of the imminent threat to the health of Russian population and the environment due to GE crops and products. This campaign was supported by some top Russian officials, including the Russian Minister of Agriculture. On June 16, 2014, the Government of the Russian Federation issued Resolution No. 548 that delayed the start of registration of GE crops for cultivation in Russia to July 1, 2017<sup>3</sup>. Never-the-less, the anti-GE campaign continued, and Federal Law No. 358, banning the cultivation of GE crops and breeding of GE animals in Russia, was passed on July 3, 2016.

The "GMO" issue is a "hot topic" in mass media, and they refer to FL 358 as a law that also bans the importation of GE organisms and products<sup>4</sup>. However, the law stipulates that the Government has such authority only when monitoring finds that a certain GE organisms or a product creates a negative impact on the environment and/or human health.

Federal Law 358 does not ban imports of GE organisms for scientific research, although industry analysts have indicated that they believe research will cease because the scientific community will not be interested in conducting expensive research without prospects for commercialization.

Federal Law 358 does not ban imports of GE organisms and products (for food and feed use) if they are already registered for food and feed use in Russia. However, Federal Law 358 provides that the Russian controlling agencies may ban imports of products if they find a threat to the environment, people, or animals, or if they determine that the imported product(s) are not registered in Russia. Russian controlling agencies, such as the Russian Federal Service for Surveillance in the Sphere of Human Wellbeing (Rospotrebnadzor) and the Federal Service for Veterinary and Phytosanitary Surveillance

<sup>&</sup>lt;sup>2</sup> For more information see FAS/Moscow GAIN report: <u>Government Resolution on GMO Registration for Environmental Release 9-25-2013.pdf</u>

<sup>&</sup>lt;sup>3</sup> For more information see FAS/Moscow GAIN report GMO Registration for Cultivation Postponed 6-27-2014.pdf

<sup>&</sup>lt;sup>4</sup> i.e. <a href="http://ria.ru/economy/20160705/1459098131.html">http://ria.ru/economy/20160705/1459098131.html</a>

(Rosselkhoznadzor – VPSS), already have this responsibility based on regulatory documents that describe their functions.<sup>5</sup> However, Federal Law 358 affixes the responsibilities under the federal law on the state regulation of genetic engineering activities.

Unofficial translation begins:

#### **RUSSIAN FEDERATION**

#### **FEDERAL LAW**

On the Amendments to Certain Legislative Acts of the Russian Federation Concerning Improvement of the State Regulation in the Area of Genetic-Engineering Activity

Adopted by the State Duma

June 24, 2016

Endorsed by the Federation Council

June 29, 2016

#### **Article 1**

To introduce the following amendments to Federal Law of July 05, 1996, #86-FZ "On the State Regulation in the Area of Gene-Engineering Activity" (Collection of Legislative Acts of the Russian Federation, 1996, No. 28, Article 3348; 2000, No. 29, Article 3005; 2009, No. 1, Article 21; 2010, No. 41, Article 5191):

- 1) in Article 1, to delete the words "and the assurance of environmental safety" and insert the words "the assurance of environmental safety and the protection of human health;"
- 2) in Article 2:
- a) to add new paragraphs 11 and 12 with the following contents:

"control of the release of genetically modified organisms into the environment --- activity of the federal executive authorities aimed at identifying and stopping violations due to an action or inaction which has caused the introduction of genetically modified organisms into the environment, as well as at eliminating consequences of identified violation;

monitoring of human and environmental exposure to genetically modified organisms and products derived with the use of such organisms or containing such organisms --- a set of measures comprising collection, processing, review and general public outreach of the information concerning effects of the exposure to genetically modified organisms and products, derived with the use of such organisms or containing such organisms, on human health and environmental status;"

- b) paragraphs from the 11<sup>th</sup> through the 13<sup>th</sup> to be renumbered as paragraphs from the 13<sup>th</sup> through the 15<sup>th</sup>, respectively;
- 3) In Article 5:
- a) to add the following paragraphs to Part 1:

<sup>&</sup>lt;sup>5</sup> For more information on the authority of Rospotrebnadzor and Rosselkhoznadzor (VPSS) see FAS/Moscow GAIN report Agricultural Biotechnology Annual 7-9-2015.pdf

"monitoring of human and environmental exposure to genetically modified organisms and products, derived with the use of such organisms or containing such organisms;

control of the release of genetically modified organisms into the environment;"

- b) Part 2, paragraph 6, to add the following wording: "including the above products imported into the territory of the Russian Federation;"
- 4) In Article 7:
- a) Part 9, after the words "such organisms," to add the following wording "including the above products imported into the territory of the Russian Federation;"
- b) to add Parts 10-13 with the following contents:

"Monitoring of human and environmental exposure to genetically modified organisms and products, derived with the use of such organisms or containing such organisms, and control of the release of such organisms into environment shall be conducted by the federal executive bodies pursuant to the procedure established by the Government of the Russian Federation.

Relations associated with exercising control over the release of genetically modified organisms into environment, making arrangements for and carrying out inspections of legal entities and individual entrepreneurs, as well as with monitoring of human and environmental exposure to genetically modified organisms and products, derived with the use of such organisms or containing such organisms, shall be subject to provisions of Federal Law of December 26, 2008, No. 294-FZ "On the Protection of Rights of Legal Entities and Individual Entrepreneurs in the Course of Exercise of State Control (Surveillance) and Municipal Control."

Based on the results of monitoring of human and environmental exposure to genetically modified organisms and products, derived with the use of such organisms or containing such organisms, the Government of the Russian Federation (RF) is entitled to place a ban on import of genetically modified organisms intended for the release into environment and/or products, derived with the use of such organisms or containing such organisms, into the territory of the Russian Federation.

Control of the import of genetically modified organisms and seeds in the territory of the Russian Federation at the check points of the Russian Federation State Border shall be exercised by a federal executive body authorized by the Russian Federation Government;"

5) To add Part 2 to Article 12 as follows:

"Violation of the Russian Federation legislation in the area of gene-engineering activity by legal entities which in the Russian Federation territory carry out gene-engineering activity, production and/or supply of products, derived with the use of such organisms or containing such organisms, consisting in the use of genetically modified organisms not in compliance with the permitted type(s) of intended use; violation of special conditions for using genetically modified organisms, e.g. in the manufacture of specific types of products; or, in the use of genetically modified organisms and/or products not registered pursuant to the established procedure, shall involve responsibility in accordance with the Russian Federation legislation."

#### **Article 2**

To add Part 4 to Article 21 of the Federal Law of December 17, 1997, No. 149-FZ "On Seed Industry" (Collection of Legislative Acts of the Russian Federation, 1997, No. 51, Article 5715; 2011, No. 30,

Article 4596) as follows:

"It is prohibited to import into the Russian Federation territory or to use for sowing (planting) the seeds of plants which have modified genetics through the application of gene-engineering methods and which contain gene-engineering material that cannot be introduced as a result of natural (spontaneous) processes, with exception of sowing (planting) such seeds in the course of expert examination and research activities."

#### Article 3

To introduce into the Russian Federation Code of Administrative Orders (Collection of Legislative Acts of the Russian Federation...)<sup>6</sup> the following amendments:

1) to add Article 6.3<sup>1</sup> as follows:

"Article 6.3<sup>1</sup>: Violation of the legislation of the Russian Federation in the Area of Genetic Engineering Activity

A violation of the legislation of the Russian Federation in the Area of Genetic Engineering Activity consisting of the use of genetically modified organisms and/or products, derived with the use of such organisms or containing such organisms, that have not been registered with the state in case where state registration is required by said legislation, or where the period of validity of the certificate on state registration has expired, or in the case where genetically modified organisms are not used in conformity with the purpose(s) for which they were registered, or where there is failure to comply with genetically modified organisms stipulated special use conditions are not complied with, e.g. in the manufacture of specific type of products, will involve imposition of a penalty on officials in the amount ranging from Ten Thousand to Fifty Thousand Rubles; on legal entities – from One Hundred Thousand to Five Hundred Thousand Rubles;"

- 2) in Article 23.1, Part 2, numbers "6.3 6.6" are to be replaced with numbers "6.3, 6.4 6.6."
- in Article 23.13, Part 1, numbers "6.3 6.7" are to be replaced with numbers "6.3, 6.4 6.7"
- 4) to add Article 23.13<sup>1</sup> as follows:

"Article 23.13: Bodies Exercising Control of the Release of Genetically Modified Organisms in the Environment

- 1. Bodies exercising control of the release of genetically modified organisms in the environment shall review cases of administrative offenses envisaged in Article 6.3<sup>1</sup> of this Code.
- 2. A right to review cases of administrative offenses on behalf of the authorities mentioned in Part 1 of this Article is granted to:
- 1) head of the federal executive body exercising control of the release of genetically modified organisms in the environment, and his/her deputies;
- 2) heads of structural units of the federal executive body exercising control of the release of genetically modified organisms in environment, and their deputies;

<sup>&</sup>lt;sup>6</sup> FAS/Moscow: The two pages referencing all concerned articles of the Russian Code of Administrative Violations can be found in the Russian text of the document.

3) heads of the territorial administrations of the federal executive body exercising control of the release of genetically modified organisms in environment, and their deputies."

#### **Article 4**

To add paragraph to Article 50, item 1 of Federal Law of January 10, 2002 No, 7-FZ "On Protection of the Environment" (Collection of Legislative Acts of the Russian Federation, 2002, No. 2, Article 133; 2011, No. 30, Article 4596) as follows:

"It is prohibited to grow or breed plants and animals whose genetics have been modified by using genetic-engineering methods and which contain genetic-engineered material that cannot be introduced as a result of natural (spontaneous) processes, with exception of growing and breeding such plants and animals in the course of expert examination and research activities."

#### **Article 5**

- 1. The Federal Law shall become effective from the date of its official publication, except Article 3 of this Federal Law.
- 2. Article 3 of this Federal Law shall become effective beginning July 01, 2017.

President of the Russian Federation

V. Putin

Round Seal
Office of the President of the
Russian Federation

Moscow, the Kremlin July 03, 2016 No. 358-FZ

End unofficial translation